Remarks

Independent claims 1 and 6 have been amended to specify that the applicator barrel has a size and shape suitable for insertion into the vagina or rectum and suitable for preventing penetration of the vaginal wall, cervix or rectum. Support for these amendments can be found in the specification at least at page 4, lines 8-19.

Claim 6 has been further amended to delete the steps of placing an applicator cap on the proximal end of the applicator barrel and then removing the applicator cap from the proximal end of the applicator barrel. These limitations have been inserted in new dependent claim 11.

Rejection Under 35 U.S.C. § 102

Claims 1, 3, 6 and 8-10 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 2,847,011 to Jones ("Jones"). Applicants respectfully traverse this rejection.

Jones discloses a disposable applicator and method of using the applicator that is different from the vaginal or rectal applicator and method of transvaginal or transrectal drug delivery defined by the claims.

The claims as amended specify that the applicator barrel has a size and shape *suitable for insertion into the vagina or rectum* and *suitable for preventing penetration of the vaginal wall, cervix or rectum*. In contrast, Jones discloses an applicator that is not suitable for insertion into the vagina or rectum. Figure 1-4 show that the end of the applicator that is designed for administration of the medicament to a patient has the same outer diameter as the rest of the applicator (*see e.g.* Figures 3 and 4). With respect to Figure 3, the specification explains that the end of the container (17) that protrudes beyond the end of the tube (11) is broken off at restriction (19) (col. 3, lines 3-4). Thus even with respect to Figure 3, the outer diameter of the

outer barrel (11) defines the outer dimension of the end of the applicator that administers the medicament. Jones' applicator has a blunt end which is generally not suitable for insertion into the vagina or rectum.

Jones does not provide dimensions for the applicators. Further, there is nothing in Jones that indicates that the applicator barrel is actually inserted into the vagina or the rectum. Rather Jones merely indicates that the composition in the applicator is dispensed or expelled into a body cavity (*see e.g.* col. 1, lines 55-58 and 62-63). Additionally, since the outer wall of Jones' applicator has the same diameter for the length of the applicator, even if Jones' applicator would be capable of being inserted into the rectum or the vaginal cavity, then the applicator would not have a shape suitable for preventing it from penetrating the vagina wall, cervix or rectum.

Jones does not disclose the volume of medicament that the applicator can contain. Therefore Jones does not disclose an applicator containing a medication chamber at the tip which is designed to contain a discrete volume of the medication, with a maximum capacity of 1 mL, as required by the claims.

With respect to claim 6 and its dependent claims, Jones does not disclose breech filling the applicator. In contrast, Jones states that the container (17) is filled through the open end (20) which may then be sealed with a slidable seal (20). The open end (20) is opposite the end that is used to administer the composition (*see e.g.* Figure 1).

Therefore independent claims 1 and 6 and dependent claims 3 and 8-10 are novel over Jones.

Rejection Under 35 U.S.C. § 103

Claim 2 was rejected under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 2,847,011 to Jones ("Jones"). Claims 4 and 5 were rejected under 35 U.S.C. § 103 as being obvious over Jones in view of U.S. Patent No. 6,224,573 to Yeager *et al.* ("Yeager"). Applicants respectfully traverse this rejection.

Claim 2 is not obvious in view of Jones

Claim 2 depends from claim 1 and further specifies that the applicator contains a flange.

As noted above, Jones discloses applicators that are structurally and functionally different from the claimed applicator. Further, it would not have been obvious to one of ordinary skill in the art to modify the applicator described in Jones to form the applicator defined by claim 2. First, Jones does not disclose any dimension of the applicator, let alone indicate that the applicator barrel is suitable for insertion into a patient's vagina or rectum. Second, Jones' applicator has one outer diameter for the entire length of the applicator. Thus, even if Jones' applicator had a suitable size for insertion into a patient's vagina or rectum, it does not have a shape suitable for preventing it from penetrating the vagina wall, cervix or rectum.

Further, Jones does not disclose the volume of medicament that the applicator can contain. Jones broadly states that "[t]he container 17 is filled with the desired volume of a medicament through the opened end 20." (col. 2, lines 63-65) This broad disclosure does not indicate that Jones is designed for the small volume (*i.e.* maximum capacity of 1 mL) required by the claims.

Jones discusses formulations for treating vaginal infections or contraception, but does not disclose the standard dosages. As of the 1950's, when Jones was filed, typical topical

formulations for contraception were spermicides, such as nonoxynol-9. Even today, nonoxynol-9 is administered in dosages greater than 1 mL (*see e.g.* Roddy, *et al.*, *JAMA*, 287:1117-1122 (2002)). Similarly, even today, typical formulations for treating vaginal infections are administered in volumes of greater than 1 mL (*e.g.* the anti-fungal agent, clotrimazole, is typically administered in dosages of 4 ml to 4.4 ml or 5 grams of cream, *see* Goodman & Gilman's: The Phamacological Basis of Therapeutics, 9th Ed., p. 1185 (1996)). Therefore there is no indication that Jones was even contemplating applicators that can contain a discrete volume of up to 1 mL, as required by the claims.

Therefore one of ordinary skill in the art would not be motivated to modify Jones to form the applicator defined by claim 2. Therefore claim 2 is not obvious in view of Jones.

Claims 4 and 5 are not obvious over the combination of Jones and Yeager

Claim 4 depends from claim 1 and further specifies that the applicator cap forms an air-tight seal with the applicator barrel. Claim 5 depends from claim 1 and further specifies that the plunger tip forms an air-tight seal with the applicator barrel.

Jones

A number of the differences between Jones' applicator and the applicator defined by independent claim 1 are discussed above.

Yaeger

Yeager discloses a disposable applicator for dispensing a desired quantity of a substantially non-runny medicament. As shown in Figures 5-7, the device contains a housing (14) which has a barrel portion (47). The barrel portion includes a generally tapered tubular wall (48) defining a housing chamber (50). As shown in Figures 2 and 7, the term "housing chamber

(50)" refers to the entire space inside the barrel portion (47) (*see also* col. 6, lines 4-6). The dispensing chamber or passageway (84) (col. 4, lines 62) is external to the housing chamber (50) (*see* Figure 7). Thus, Yeager's housing chamber does not comprise a medication chamber at its proximal end, as required by independent claim 1.

Further, in Yeager's device, the plunger only fits in the housing chamber (50). It does not fit in the dispensing chamber or passageway (84). In contrast, the claims specify that the applicator barrel contains a medication chamber at its proximal end. Claim 5 specifies that the plunger forms an airtight seal with the applicator barrel. Thus, the plunger must form an airtight seal with the medication chamber, as well. In contrast, Yeager's device is designed to prevent the plunger from fitting in the dispensing chamber or passageway (84).

The combination of Jones and Yeager

The combination of Jones with Yeager would not make claims 4 and 5 obvious to one of ordinary skill in the art. As noted above, Jones discloses applicators that are structurally and functionally different from the claimed applicator. Further, it would not have been obvious to one of ordinary skill in the art to modify the applicator described in Jones to form the applicator defined by claim 2. First, Jones does not disclose any dimension of the applicator, let alone indicate that the applicator barrel is suitable for insertion into a patient's vagina or rectum. Second, Jones' applicator has one outer diameter for the entire length of the applicator. Thus, even if Jones' applicator had a suitable size for insertion into a patient's vagina or rectum, it does not have a shape suitable for preventing it from penetrating the vagina wall, cervix or rectum.

Yeager has a completely different shape from the shape of the Jones applicator. Additionally Yeager's applicator has a number of differences from the applicator defined by

claims 4 and 5. There is nothing in either of the references which would motivate one of ordinary skill in the art to completely modify the structures of the applicators to create the claimed applicator. To do so at this time would result in the use of improper hindsight analysis, *i.e.* using the pending claims as the starting point and then picking and choosing portions from each disclosure.

Further, with respect to claim 5, Yeager's applicator is designed to prevent the plunger from traveling within the medication chamber, which is part of the applicator barrel (as required by claim 1 and its dependent claims). Therefore Yeager teaches away from a plunger that forms an airtight seal with the applicator barrel, as defined by claim 5.

Therefore claims 4 and 5 are not obvious in view of Jones in combination with Yeager.

Applicants believe that this amendment places the claims in condition for allowance. However, in the event that the Examiner has further objections to the claims, Applicants respectfully request a telephone interview with the Examiner.

Allowance of claims 1-6 and 8-11, as amended, is respectfully solicited.

Respectfully submitted,

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